K101729

Section 5.0: 510(k) Summary

SEP 23 2010

5.1 Administrative Information

Name:	NeoMetrics, Inc.
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FDA Registration Number:	2135342
Date:	April 2, 2010

5.2 Device Information

Name of Device:	NeoWire PTA/PTCA Guidewire
Common Name:	Guides, Guidewires, or spring Guidewires
Classification Name:	Catheter Guide Wire (870.1330)
Product Code:	DQX

5.3 Predicate Device Information

The following commercially available guidewires are predicate devices for NeoWire.

510(k) Number	Trade or Model Name	Manufacturer
K070150	VascuPuncture PICC Guidewire	NeoMetrics, Inc.
K983927	Zinger Guidewire	Medtronic
K013024	Selectiva	NeoMetrics, Inc.
K082304	Roll-X	St. Jude Medical
K081337	Approach CTO	Cook

5.4 Device Description

NeoWire is a steerable guidewire constructed of a nitinol alloy core with a coiled segment on the distal end. The core wire is either PTFE coated or uncoated and the wire may also contain silicone or hydrophilic lubricious coatings. This distal end of the wire can be shapeable and is radiopaque.

5.5 Intended Use

The NeoWire Guidewire is intended to facilitate the introduction and placement of catheters and interventional devices within the coronary and/or peripheral vasculature. Models with Stiff tips (> 9g) are intended for peripheral use only. Models with Floppy, Soft, and Medium tips (≤ 9g) are intended for peripheral or coronary use. The guidewire is not intended for use in the cerebral vasculature.

5.6 Technological Characteristics

A comparison of the characteristics of the proposed device to the predicate devices show the proposed device to have the following same or similar technological characteristics to the devices which have received 510(k) clearance:

- Same intended use;
- Same operating principle;
- Same shelf life and sterilization process;
- Similarities in Design, Material Types, and Technology include:
    - Nominal diameters: 0.014" and 0.018"
    - Similar Lengths: 80, 180 – 190, and 300cm
    - Nitinol alloy core wires
    - Distal radiopaque coils
    - Flexible, shapeable distal tip segments
    - Joined by a combination of adhesive and welds
    - Lubricious coatings

To ascertain similarity, the following performance testing was conducted on both the proposed device and the predicate devices:

- Guidewire Dimensions (overall length, radiopaque tip length, and diameter) per FDA Coronary and Cerebrovascular Guidewire Guidance January 1995
- Torqueability and Torque Strength per FDA Coronary and Cerebrovascular Guidewire Guidance January 1995
- Coating Adherence per FDA Coronary and Cerebrovascular Guidewire Guidance January 1995
- Tip Flexibility per FDA Coronary and Cerebrovascular Guidewire Guidance January 1995
- Sterile Package Integrity per ASTM F 1929-98
- Sterile Package Integrity per ASTM F 88-09
- Reverse Bend (Fatigue Failure) per ISO 11070
- Tensile testing per ISO 11070
- Fracture Resistance per ISO 11070
- Corrosion Resistance per ISO 11070
- Tip Load per NeoMetrics' test method TM-3010
- Rail Support per NeoMetrics' test method TM-3002

Due to the destructive nature of some of the tests and the availability of predicate devices not all testing was conducted on each predicate device, however competitive devices were tested along with the proposed device in each test.

5.7 Summary of Non-Clinical Testing

Non-clinical testing of the NeoWire Guidewire includes bench testing, biocompatibility testing, shelf-life and packaging testing and sterilization evaluation. Bench testing, shelf-life testing, and sterilization testing were conducted on NeoWire. Biocompatibility testing was conducted on NeoWire and leveraged from other previously cleared NeoMetrics products. A summary table of the test data source is shown:

Tested and Leveraged Biocomaptibility Data								
Test Guidance Document	ISO 10993-4	ISO 10993-4 (ASTM Guideline F-756-00)	ISO 10993-5	ISO 10993-11	ISO-10993-10	ISO 10993-10		
Material	Partial Thromboplastin Time (PTT)	ASTM Hemolysis Assay Direct Contact Method	MEM Elution Assay with L-929 Mouse Fibroblast Cells (Cytotoxicity)	Acute Systemic Injection Test	Intracutaneous Reactivity Test	Guinea Pig Maximization Sensitization Test	Complement Activation	In Vivo Thrombosis (Thrombo-genicity)
Core Wire	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire
Hydrophilic Coating	Leveraged	Leveraged	Leveraged	Leveraged	Leveraged	Leveraged	Tested on NeoWire	Tested on NeoWire
Silicone Coating	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Leveraged	Leveraged
Proximal Coil (dual coil designs)	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Leveraged	Leveraged
Radiopaque Distal Coil (Option 1)	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire
Radiopaque Distal Coil (Option 2)	Leveraged	Leveraged	Leveraged	Leveraged	Leveraged	Leveraged	Leveraged	Leveraged
Adhesive	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Leveraged	Leveraged
PTFE Coating	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire	Tested on NeoWire

Results of this testing demonstrate that the guidewire design meets the product specifications and intended uses.

5.8 Substantial Equivalence Conclusion

The NeoWire Guidewire described in this 510(k) is substantially equivalent to the devices listed in section 5.3. The intended use, design, material types, technology, and performance of the NeoWire Guidewire are equivalent to the predicate devices. There are no differences between devices which would raise issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NeoMetrics, Inc.
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

SEP 23 2010

Re: K101729
Trade/Device Name: NeoWire PTA/PTCA Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: September 7, 2010
Received: September 8, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101729

Section 4: Indications for Use Statement

SEP 2 3 2010

Indications for Use

510(k) Number (if known): unavailable

Device Name: NeoWire PTA/PTCA Guidewire

Indications for Use:

The NeoWire Guidewire is intended to facilitate the introduction and placement of catheters and interventional devices within the coronary and/or peripheral vasculature. Models with Stiff tips (> 9g) are intended for peripheral use only. Models with Floppy, Soft, and Medium tips (≤ 9g) are intended for peripheral or coronary use. The guidewire is not intended for use in the cerebral vasculature.

Prescription Use: X AND/OR Over-The-Counter Use: _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number: K101729